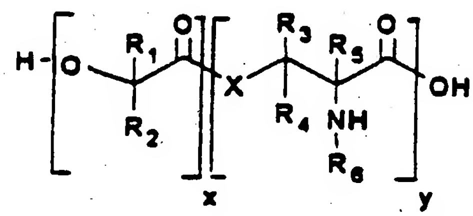
CLAIMS

What we claim is:

1. A biodegradable, biocompatible polymer having a backbone of the general formula:



wherein:

R_1, R_2, R_3, R_4, and R_5 are selected independently and are selected from H, linear or branched alkyl groups;

R_6 is selected from H, an amine protecting group, a spacer molecule or a biologically active species;

X is selected from an O or S group; and

x and y are integers.

2. The polymer of claim 1 wherein x and y are integers of values such that the polymer is comprised at least about 95% of α-hydroxy acid residues.

3. The polymer of claim 1 which is derived by copolymerization of monomers comprising at least one α-hydroxy acid and at least one pseudo-α-amino acid.

4. The polymer of claim 3, wherein the at least one α-hydroxy acid has the formula $R_1R_2COHCO_2H$, wherein the R_1 and R_2 groups are H, linear or branched alkyl units, the alkyl unit being represented by the formula C_nH_{2n+1}, where n = integer of about 1 to 10.

5. The polymer of claim 4, wherein the α-hydroxy

acids comprise a mixture of α-hydroxy acids, one of said mixture of α-hydroxy acids having R_1 and R_2 groups which are hydrogen and the other of said mixture of α-hydroxy acids having an R_1 group which is CH_3 and R_2 group which is H.

6. The polymer of claim 3, wherein the at least one pseudo-α-amino acid has the formula $R_5CHNHR_6CO_2H$, wherein the R_5 group is a hydroxyl methyl or methyl thiol group and R_6 is an amine protecting group.

7. The polymer of claim 6, wherein the amine protecting group is selected from the group consisting of carbobenzyloxy (CBZ or Z), benzyl (Bn), para-methoxybenzyl (MeOBn), benzyloxymethoxy (BOM), tert-butyloxycarbonyl (t-BOC) and [9-fluorenylmethyl oxy]carbonyl (FMOC).

8. The polymer of claim 3, wherein the at least one α-hydroxy acid is selected from the group consisting of L-lactic acid, D,L-lactic acid, glycolic acid, hydroxy valeric acid and hydroxybutyric acid.

9. The polymer of claim 3, wherein the at least one pseudo-α-amino acid is derived from serine.

10. The polymer of claim 1, wherein said polymer is poly-D,L-lactide-co-glycolide-co-pseudo-Z-serine ester (PLGpZS).

11. The polymer of claim 1, wherein said polymer is poly-p,L-lactide-co-glycolide-co-pseudo-serine ester(PLGpS).

12. The polymer of claim 1, wherein R_6 is at least one biologically active species.

13. The polymer of claim 12, wherein R_6 is at least one spacer molecule to which at least one biologically active species is coupled.

14. The polymer of claim 13, wherein the spacer molecule is selected from α-hydroxy acids represented by the formula $R_7R_8COHCO_2H$, wherein the R_7 or R_8 groups are independently H, linear or branched alkyl units and pseudo-α-amino acids represented by the formula $R_9CHNHR_{10}CO_2H$, wherein the R_9 group is a hydroxyl methyl or methyl thiol group and R_{10} is an amine protecting group.

15. The polymer of claim 12, wherein the at least one biologically active species is selected from the group consisting of cell bioadhesion groups, macrophage stimulators, poly amino acids and polyethylene glycol.

16. The polymer of claim 1 having a molecular weight of about 5000 to about 40,000 daltons.

17. A process for making a biodegradable, biocompatible polyester, which comprises co-polymerizing at least one α-hydroxy acid monomer and at least one pseudo-α-amino acid monomer.

18. A process for making a biodegrable, biocompatible polymer of the formula shown in claim 1, which comprises;

- forming a mixture of monomers comprising at least one α-hydroxy acid and at least one pseudo-α-amino acid having an amine protecting group with an organic solvent solution of an esterification catalyst under inert atmospheric conditions;
- copolymerizing said monomers; and
- isolating the resultant polymer.

19. The process of claim 18, wherein the polymer formed is deprotected by solid phase catalytic reduction or acid catalysis.

20. The process of claim 19, wherein said deprotection is by acid catalysis in the presence of hydrogen bromide in acetic acid solution.

21. The process of claim 18, wherein said catalyst is stannous 2-ethylhexanoate.

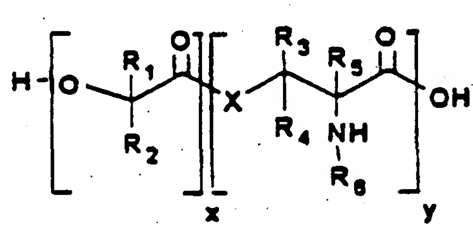
22. The process of claim 18, wherein said polymerization is carried out at a temperature of about 120°C for about 28 hours.

23. The process of claim 18, wherein said organic solvent is anhydrous chloroform.

24. The process of claim 18, wherein said process further comprises forming the polymer into a film.

25. The process of claim 18, wherein said process further comprises forming the polymer into microparticles.

26. A particulate carrier for delivery of biologically active materials to a host, said carrier comprising a polymer having a backbone of the general formula:



wherein:

R_1, R_2, R_3, R_4 and R_5 are selected independently and are selected from H, linear or branched alkyl groups;

R_6 is selected from H, an amine protecting group, a spacer molecule or a biologically active species;

X is selected from an O or S group; and

x and y are integers.

27. The particulate carrier of claim 26, wherein said carrier has a particle size of about 1 to 50 μM.

28. The particulate carrier of claim 27 wherein said polymer has a molecule weight of about 5,000 to about 40,000 daltons.

29. The particulate carrier of claim 28 wherein at least about 95% of the polymer is comprised of α-hydroxy acid residues.

30. A composition comprising the particulate carrier of claim 26 and at least one biologically active material entrapped therein.

31. A composition comprising the particulate carrier of claim 26 and at least one biologically active material physically mixed therewith.

32. The composition of claim 30 or 31, wherein said at least one biologically active material is capable of eliciting an immune response.

33. The composition of claim 32, wherein said at least one biologically active material comprises at least one *Haemophilus influenzae* protein.

34. The composition of claim 33, wherein said *Haemophilus influenzae* protein is selected from the group consisting of a non-proteolytic Hin-47 analog, D15, P1, P2, P6 and mixtures thereof.

35. The composition of claim 32, wherein said at least one biologically active material comprises at least one

influenza virus or influenza virus protein.

36. The composition of claim 35 wherein said influenza virus comprises a multivalent influenza virus vaccine.

37. The composition of claim 35 wherein said influenza virus comprises a monovalent influenza virus vaccine.

38. The composition of claim 35 wherein said influenza virus protein comprises a influenza virus monovalent protein vaccine.

39. The composition of claim 32 wherein said at least one biologically active material comprises at least one *Moraxella catarrhalis* protein.

40. The composition of claim 39 wherein said at least one *M. catarrhalis* protein is a Tbp2 protein of *M. Catarrhalis*.

41. The composition of claim 32 wherein said at least one biologically active material comprises at least one *Helicobacter pylori* protein.

42. The composition of 41 wherein said *H. pylori* protein comprises Urease.

43. The composition of claim 26 further comprising at least one adjuvant entrapped therein.

44. The composition of claim 26 further comprising at least one adjuvant mixed therewith.

45. The composition of claim 43 or 44, wherein said adjuvant is selected from the group consisting of lipopeptides, mineral salts, lipids, glycolipids, carbohydrates and combinations, derivatives and mixtures thereof.

46. The composition of claim 45 wherein said adjuvant is an organic solvent soluble adjuvant.

47. The composotion of claim 46 wherein said adjuvant is selected from the group consisting of BAY R1-005, tripalmitoyl cysteine and DC-chol.

48. The composition of claim 45 wherein said adjuvant is a water soluble adjuvant.

49. The composition of claim 48 wherein said adjuvant is a polymeric water soluble adjuvant.

50. The composition of claim 49 wherein said polymer adjuvant is PCPP.

51. The composition of claim 49 wherein said water soluble adjuvant is a mucosal adjuvant.

52. The composition of claim 51 wherein said mucosal adjuvant is CT-X.

53. The composition of claim 51 wherein said mucosal adjuvant is LT.

54. The composition of claim 30 or 31, wherein said carrier comprises a matrix having a particle size of about 1 to 50 μM.

55. A process for making a particulate carrier for the delivery of at least one biologically active material to a host, comprising the steps of:

(a) mixing an organic solvent phase comprising an α-hydroxy acid polymer or copolymer with an aqueous composition comprising dispersed or dissolved biologically active material to form a first water-in-oil emulsion;

(b) dispersing the first water-in-oil emulsion into an aqueous detergent phase to form a second water-in-oil-in-water double emulsion;

(c) removing water from the second double

emulsion to form microspheres; and

(d) collecting the microspheres and having said biological material entrapped therein.

56. The process of claim 55, wherein said polymer is selected from the group consisting of poly-D-, L-lactide-co-glycolide (PLG), poly-D,L-lactide-co-glycolide-co-pseudo-Z-serine ester (PLGpZS) and poly-D,L-lactide-co-glycolide-co-pseudo-serine ester (PLGpS).

57. The process of claim 55, wherein said organic solvent is selected from the group consisting of dichloromethane, ethyl acetate, acetone and mixtures thereof.

58. The process of claim 58, wherein said aqueous detergent phase comprises at least one non-ionic emulsion stabilizer.

59. The process of claim 58, wherein said at least one non-ionic emulsion stabilizer is selected from the group consisting of poly vinyl alcohol, methyl cellulose and Triton X-100.

60. The process of claim 55, wherein said first water-in-oil emulsion additionally comprises at least one organic solvent soluble adjuvant.

61. The process of claim 60 wherein said organic solvent soluble adjuvant is lipophilic.

62. The process of claim 61, wherein said adjuvant is selected from the group consisting of BAY R1-005, tripalmitoyl cysteine and DC-Chol.

63. The process of claim 55 wherein said first water-in-oil emulsion additionally comprises at least one water soluble adjuvant.

64. The process of claim 63 wherein said water soluble adjuvant is a polymer water soluble adjuvant.

65. The process of claim 64 wherein said polymeric water soluble adjuvant is PCPP.

66. The process of claim 62 wherein said water soluble adjuvant is a mucosal adjuvant.

67. The process of claim 63 wherein said mucosal adjuvant is CT-X.

68. The process of claim 66 wherein said mucosal adjuvant is LT.

69. The process of claim 55, wherein said first water-in-oil emulsion additionally comprises at least one surfactant.

70. The process of claim 69, wherein said surfactant is selected from the group consisting of sucrose, mannose, trehalose and gelatin.

71. An immunogenic composition comprising the particulate carrier of claim 26, an immunogen, and a physiologically acceptable carrier therefor.

72. A method of producing an immune response in a host comprising administering the immunogenic composition of claim 71 to said host.

73. The method of claim 72, wherein said composition is administered mucosally or parenterally.

74. The method of claim 72, wherein said immune response is an antibody response.

75. The method of claim 74, wherein said antibody response is a local or serum antibody response.